Opportunity Title: FDA Postdoctoral Fellowship - Advancing Regulatory Science through Real-World Evidence: Synthesis, Gap Analysis, and Strategic Direction
Opportunity Reference Code: FDA-CDER-2026-0106

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2026-0106

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click APPLY.***

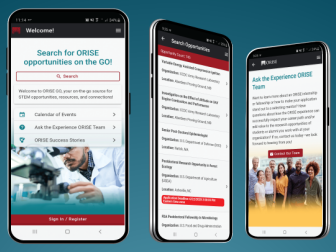
A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDER@orau.org. Please include the reference code for this opportunity in your email.

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Application Deadline 5/1/2027 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

FDA Office and Location: Multiple research opportunities are available in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) located in White Oak, Maryland.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

Research Project: You will have the opportunity to join projects with the following goals:

- Systematically characterize and synthesize the FDA Real-World Evidence (RWE) demonstration project portfolio
  - Conduct a comprehensive review of completed and ongoing demonstration projects across key domains (data considerations, study design, and analytic methods) to identify common themes, methodological approaches, and regulatory use cases. Develop a structured evidence map summarizing project aims, outputs, and contributions to advancing RWE for regulatory decision-making.
- Identify cross-cutting insights and best practices to inform regulatory science

    - Extract and synthesize key learnings from the portfolio, including successful approaches, methodological innovations, and recurring challenges. Translate findings into actionable best practices to support consistent, appropriate use of RWD/RWE in FDA regulatory contexts. Publish key learnings in a peer reviewed journal article.
- Conduct a gap analysis and develop a forward-looking research and funding strategy
    - Assess unmet needs and gaps across the current portfolio (e.g., underrepresented therapeutic areas, populations, data sources, or methodological approaches). Provide findings to FDA staff to guide future FDA funding priorities, demonstration projects, and collaborative initiatives that maximize the impact of RWE on regulatory decision-making.

Learning Objectives: Under the guidance of a mentor you have the following learning opporunities:

- Regulatory science landscape: You will become familiar with the role of RWE in regulatory science, gaining exposure to priority research areas and emerging methodological developments that shape FDA's approach to real-world evidence.
- Review and synthesis skills: You will develop skills in the systematic review and synthesis of a portfolio of FDA Real-World Evidence (RWE) demonstration projects across domains such as data considerations, study design, and analytic methods.
- Thematic and methodological analysis: You will build competency in identifying cross-cutting themes, methodological innovations, and recurring challenges that inform the advancement of RWE in regulatory decision-making.
- Translation of findings into practice: You will practice translating synthesized findings into actionable best practices that support the consistent and appropriate use of Real-World Data (RWD) and RWE in FDA regulatory contexts.
- Gap analysis: You will develop skills in conducting gap analyses to identify underrepresented therapeutic areas, populations, data sources, and methodological approaches within a research portfolio.
- Scientific communication: You will strengthen your ability to communicate key findings and recommendations through peer-reviewed publications, conference presentations and strategic reports.

Mentor: The mentor for this opportunity is Marie Bradley (marie.bradley@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the

availability of funds.

Level of Participation: The appointment is full time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;

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- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The candidate should have received or currently be pursuing a doctoral degree (PhD or equivalent) in one of the relevant fields (epidemiology, data science, mathematics, statistics). Degree must have been received within the past five years or is anticipated to be completed by August 31, 2026. Candidates with a clinical doctorate (e.g., PharmD, MD) and relevant experience will also be considered.

Preferred Skills/ Knowledge:

- Knowledge of epidemiological study design and pharmacoepidemiology, particularly as applied to drug safety, effectiveness, or comparative effectiveness research in regulatory or public health settings
- Experience conducting epidemiologic research using real-world data sources such as administrative healthcare claims data, electronic health records or registry data in a research or regulatory context
- Experience conducting systematic reviews, scoping reviews, or evidence synthesis
- Strong scientific writing and communication skills**, including** experience preparing peer-reviewed manuscripts, technical reports, or policy-relevant summaries for diverse audiences.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 8/31/2026 11:59:00 PM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

Affirmation I am a U.S. Citizen; or I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)

and

I have read the FDA Ethics Requirements.